

Attorney Docket No.: 3985.240-US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of: Havelund et al.

ECH DENTER 1600 2900

Application No.: 09 398,365

Group Art Unit: 1637

Filed: September 17, 1999

Examiner: Siew, J.

Confirmation No: 9987

For: Acylated Insulin

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents Washington, DC 20231

Sir:

In accordance with 37 C.F.R. 1.56, 1.97 and 1.98, Applicants submit herewith references which they believe may be material to the patentability of this application and with respect to which there may be a duty to disclose in accordance with 37 C.F.R. 1.56.

While the references may be "material" under 37 C.F.R. 1.56, it is not intended to constitute an admission that the references are "prior art" unless specifically designated as such.

The filing of this Information Disclosure Statement shall not be construed as a representation that no other material references than those listed exist or that a search has been conducted.

The references are listed in Form PTO-1449 which is in accordance with the requirements of M.P.E.P. 609. A copy of the references is also enclosed.

The references are as follows:

4. US 4,645,740

- 5. DE 22 09 835
- 6. EP 0 127 535 A2
- 7. EP 0 511 600 A2
- 8. Muranishi et al., Journal of Controlled Release, Vol. 19, pp. 179-188 (1992)
- 9. Brange J., Galenics of Insulin, pp. 18-100 (1987)
- 10. Blundell T. et al., The Structure in the Crystal and Its Reflection In Chemistry and Biology, Vol. 26, pp. 279-402 (1972)
- 11. Markussen et al., Prot. Eng., Vol. 2., pp. 157-166 (1988)
- 12. Brunfelt, ACTA Endocrinol, Vol. 61, pp. 561-576 (1969)
- 13. Markussen, J. et al., diabetologia 39: 281-288 (1996)
- 14. Kurtzhals et al., J. Pharm. Sci. 85(3): 04-308 (1996)
- 15. Hashimoto et al., Pharmaceutical Research 6(2): 171-176 (1989)
- 16. Markussen et al., Protein Engineering 1(3): 205-213 (1987)
- 17. US 3,868,356

It is respectfully requested that these references be considered by the Patent and Trademark Office in its examination of the above-identified application and be made of record therein. The Examiner is also invited to contact the Undersigned if there are any questions concerning this paper or the attached references.

The information disclosure statement submitted herewith is being filed within three months of the filing date of a national application or date of entry into the national stage of an international application or **before** the mailing date of a first Office action on the merits, or **before** the mailing date of a first Office action after the filing of a request for continued examination 37 C.F.R. \$ 1.97(b). Therefore, no fee is due

Respectfully submitted.

Date: September 19, 2002

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